UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PARTIALLY EXCLUDE OPINIONS OF DEFENSE CLASS EXPERT TIMOTHY E. KOSTY

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Mr. Timothy Kosty—a pharmacist with nearly four decades of experience working in the pharmacy industry, including in the upper-level management of chain retail pharmacies and pharmacy benefit managers ("PBMs")—primarily opines that the pharmaceutical industry is "highly complex," involving "many different intermediaries that hold individual contractual arrangements, which govern the distribution of and payment for pharmaceutical products." (Rep. of Timothy E. Kosty ("Kosty Rep.") ¶ 29, Jan. 12, 2022 (Pls.' Br. Ex. 1).) Plaintiffs concede that these opinions regarding "industry practice" are admissible and outside the scope of their motion. (Pls.' Br. at 1.) Rather than challenge these core affirmative conclusions, Plaintiffs seek to exclude three of Mr. Kosty's opinions that directly rebut their own experts' opinions. Plaintiffs' arguments are meritless.

First, Plaintiffs argue that Mr. Kosty is not qualified to critique their expert Dr. Rena Conti's opinion that the lifesaving valsartan-containing drugs ("VCDs") at issue in this litigation are categorically worthless. But Mr. Kosty's nearly four decades of real-word experience in the pharmacy industry more than qualify him to opine about the value that third-party payors ("TPPs") and consumers ascribe to prescription medications. Plaintiffs also argue that Mr. Kosty somehow accepted Dr. Conti's theory that the VCDs are categorically worthless. He did no such thing. Rather, when asked, Mr. Kosty agreed that ***if*** it were true that the VCDs had no value, ***then*** the proper measure of damages would be a refund. That is not an

endorsement of the question's premise. Further, Plaintiffs' argument that Mr. Kosty should not be allowed to opine on Dr. Conti's failure to account for certain offsets or costs in her damages models because Mr. Kosty did not specifically "quantify" those costs himself misunderstands the burden of proof at class certification. Mr. Kosty is free to identify the flaws in ***Plaintiffs'*** expert's opinions without offering his own calculations, quantifications or models.

Second, Plaintiffs challenge Mr. Kosty's opinions rebutting their expert Ms. Laura Craft's ascertainability-related opinions. Essentially, Plaintiffs contend that Mr. Kosty made "admissions" at his deposition that undermine his opinion. Even if this were accurate (and it is not), Plaintiffs' arguments would, at most, affect the weight of such evidence, not its admissibility. Plaintiffs also complain that Mr. Kosty did not formally "quantify" or "test" certain propositions, but once again, these critiques misapprehend the role of defense experts, who are permitted to highlight the flaws of Plaintiffs' experts rather than present their own calculations or models.

Third, Plaintiffs also challenge Mr. Kosty's opinion that TPPs do not consider statements in the Orange Book to be actual warranties, although the basis of their challenge is unclear. Mr. Kosty has extensive experience to support this opinion,

having served on pharmacy and therapeutic ("P&T") committees himself.[1] And although Plaintiffs also appear to question one source of Mr. Kosty's opinion, that is an issue for cross-examination, not a proper ground for exclusion, especially since Mr. Kosty cited multiple other sources that Plaintiffs fail to mention.

For all of these reasons, discussed in greater detail below, Plaintiffs' motion is meritless and should be rejected.

BACKGROUND

Mr. Kosty earned a bachelors' degree in pharmacy from The Ohio State University and a masters' degree in business administration from Pennsylvania State University. After graduating, Mr. Kosty spent more than a decade working in upper-level management at various chain pharmacies. Mr. Kosty then helped create a pharmacy benefit manager ("PBM"), TDI Managed Care Services, and "managed its administrative functions" for three years. (Kosty Rep. ¶ 3.) In 1996, Mr. Kosty co-founded Pharmacy Healthcare Solutions, a management consulting firm that works with a broad swath of the pharmacy industry, including pharmaceutical manufacturers, health plans, PBMs, retail, mail, and specialty pharmacies and technology companies. (*Id.* ¶ 2; Dep. of Timothy E. Kosty ("Kosty Dep.") 36:18-

[1] A P&T committee is the independent committee within a PBM or TPP "that assesses the clinical attributes of a drug" and determines whether it will be included in a formulary—i.e., the list of drugs the PBM or TPP is willing to pay for. (Kosty Rep. ¶ 65.)

37:18, Feb. 24, 2022 (Pls.' Br. Ex. 2).) He continues to work with a successor firm today. (Kosty Rep. ¶ 2.) In his various positions, Mr. Kosty has managed and implemented pharmacy benefit programs, negotiated the terms and conditions of PBM contracts, and served on P&T committees as an ex officio member. (*See id*. ¶ 5.) He has advised on more than a dozen projects that involved the integration and combination of claims data across different business entities, and the challenges and processes associated with such tasks. (Kosty Dep. 366:19-367:15.)

Mr. Kosty's opinions are "bas[ed] on [his] experience, knowledge, and review of evidence." (Kosty Rep. ¶ 28.) He describes the "highly complex" pharmaceutical industry, including the supply chain, and the sophisticated arrangements that "govern the distribution of and payment for pharmaceutical products" such as the VCDs at issue in this litigation. (*Id.* ¶ 29.) He explains the "many different types of payors that provide prescription drug coverage" (*id.* ¶¶ 42-57), and the distribution and payment methods for generic medications (*see id.* ¶¶ 35-41). And he also describes the "variation[s]" in TPP plan design and in prescription drug costs. (*Id.* ¶¶ 58-82.) Plaintiffs do not challenge any of these opinions.

Based on his understanding of the complexities of the pharmaceutical market, Mr. Kosty critiques the "overly simplistic" opinions advanced by certain of Plaintiffs' experts. (*Id.* ¶ 29.) He opines that Dr. Conti's damages calculations for the consumer economic loss and TPP classes are contrary to pharmaceutical industry

norms and that "her proposed methodology fails to account for the complexities" of that industry. (*Id.* ¶ 163.) In particular, he explains that Dr. Conti's core assumption—that the VCDs at issue in this litigation are categorically worthless—is "inconsistent with the sources of value that are considered by . . . the pharmaceutical industry." (*Id.*; *see generally id.* ¶¶ 164-174.) He also explains that Dr. Conti's calculations "do not reflect the prices paid by [the] proposed [TPP and consumer] class members, or the revenues and costs" to Pharmacy and Wholesaler Defendants (*id.* ¶ 163), and that she failed to account for a host of factors relevant to what those class members paid for the medications, such as substantial government subsidies and after-the-fact refunds (*see id.* ¶¶ 175-180). Finally, he addresses fundamental flaws in Dr. Conti's unjust enrichment models, such as her failure to account for Pharmacy and Wholesaler costs and offsets and her apparent ignorance of the individualized contracts relevant to Wholesaler cost structure. (*See id.* ¶¶ 181-194.)

Mr. Kosty also critiques opinions offered by Ms. Craft, whom Plaintiffs designated to testify about the supposed administrative feasibility of identifying the members of all three classes. Mr. Kosty opines that Ms. Craft "fails to recognize the many limitations of the available data" (*id.* ¶ 30), and that, in actuality, "individualized inquiry [would be] required to identify class members" (*id.* ¶ 88). Specifically, he explains that the lack of available data and "complex contractual

relationships" between entities make identifying TPP class members infeasible (*see id.* ¶¶ 90-118), and that individual review of prescription histories would be required to determine whether patients qualify for the medical monitoring class (*see id.* ¶¶ 119-126). He further explains that to the extent necessary data do exist, Ms. Craft ignores difficulties associated with obtaining and combining them (*see id.* ¶¶ 152-161), and with applying class exclusions for state government TPPs and for Defendants' employees and personnel (*see id.* ¶¶ 127-139). He also addresses challenges identifying members of the consumer and TPP subclasses with respect to their claims against the Wholesaler Defendants, an opinion Plaintiffs do not challenge. (*See id.* ¶¶ 140-151).

Finally, Mr. Kosty states that Dr. Panagos "mischaracterizes P&T committees' use of the Orange Book"—a list of FDA-approved medications, including generic equivalents of brand-name drugs. (*Id.* p. 99 (capitalization altered).) While the Orange Book is one of several sources consulted, such committees do not treat it as a warranty. (*See id.* ¶¶ 195-203.)

ARGUMENT

Rule 702 provides that expert testimony is admissible if the witness is qualified and the opinion is "based on sufficient facts or data" and "the product of reliable principles and methods" that have been "reliably applied . . . to the facts of

the case." Fed. R. Evid. 702. The Third Circuit has explained that "Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404-05 (3d Cir. 2003) (citation omitted).

A "broad range of knowledge, skills, and training qualify an expert." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (citation omitted). Importantly, "[i]t is not the trial court's responsibility to determine the best possible training for an expert and restrict testimony to those who possess it." *De La Cruz v. V.I. Water & Power Auth.*, 597 F. App'x 83, 91 (3d Cir. 2014); *see also Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996) ("It is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate."); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, No. 09-290, 2012 WL 6562221, at *4, *11 (W.D. Pa. Dec. 15, 2012) (similar), *aff'd*, 807 F.3d 1283 (Fed. Cir. 2015). Moreover, because "a witness may be qualified based solely on practical experience," "[f]ormal qualifications, such as a degree in a particular field, are . . . not required." *In re Actiq Sales & Mktg. Pracs. Litig.*, No. 07-4492, 2014 WL 3572932, at *3-4 (E.D. Pa. July 21, 2014).

Once an expert has been deemed qualified, the proponent must also show that "the process or technique [he or she] used in formulating the opinion is reliable."

Pineda, 520 F.3d at 244 (citations omitted). "[T]he grounds for [an] expert's opinion merely have to be good, they do not have to be perfect." *De La Cruz*, 597 F. App'x at 91 (citation omitted).

Finally, the expert testimony must fit the facts of the case. *See Schneider*, 320 F.3d at 404-05. "In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Id.* As the Supreme Court explained, this "'helpfulness' standard requires a valid scientific connection to the pertinent injury as a precondition to admissibility." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

Although all experts must satisfy the *Daubert* standard, defense experts "have a less demanding task." *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2021 WL 2352016, at *14 (E.D. Pa. June 9, 2021) (quoting *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007)). This is so because "the defense d[oes] not bear" the burden of proof either on the substantive merits of the lawsuit or with regard to the propriety of class certification. *Holbrook*, 80 F.3d at 786. As a result, defense experts need not "produce models or methods of their own." *Winn-Dixie Stores*, 2021 WL 2352016, at *14 (citation omitted).

All of Mr. Kosty's opinions easily satisfy the applicable standards.

I. MR. KOSTY'S OPINIONS CRITIQUING DR. CONTI'S DAMAGES MODEL ARE WELL SUPPORTED AND ADMISSIBLE.

Based on his 39 years of experience, Mr. Kosty opines that Dr. Conti's assertion that lifesaving VCDs were "worthless" because they might have contained certain impurities "is inconsistent" with industry realities, and that her models generally fail to accurately account for actual revenues or costs. Plaintiffs attack these opinions on qualifications and reliability grounds, but none of their criticisms warrants exclusion.

A. Mr. Kosty Is Qualified To Testify On Issues Related To Damages.

Plaintiffs first argue that Mr. Kosty is "unqualified to speak to economic damages calculations and modeling" because his expertise pertains to pharmacy operations and claims data, not economics. (Pls.' Br. at 5.) But Mr. Kosty's extensive real-world experience in the pharmacy industry more than qualifies him to opine that neither TPPs nor patients regard effective medicine as categorically worthless, and that the pricing structure in the pharmaceutical industry involves a host of factors beyond those Dr. Conti considered. *See, e.g.*, *SIS, LLC v. Stoneridge Holdings, Inc.*, No. 1:17-cv-01816-SDG, 2021 WL 2650355, at *2 (N.D. Ga. May 28, 2021) (finding damages expert qualified despite lack of "specialized training in calculating damages" based on his "experience in" a "niche industry"); *Ultraflo Corp. v. Pelican Tank Parts, Inc.*, No. H-09-0782, 2013 WL 12137088, at *2 (S.D. Tex. Sept. 25, 2013) (finding expert qualified to "rebut[] the opinions of [p]laintiff's

experts on [their] damage model and damage calculations" though it was not his "primary area of expertise").[2]

Plaintiffs acknowledge Mr. Kosty's 39 years of industry experience as a "pharmacist and consultant." (Pls.' Br. at 4.) This experience is more than sufficient for him to testify regarding "sources of value that are considered by . . . the pharmaceutical industry" (Kosty Rep. ¶ 163), and the cost and price structures in the industry that Dr. Conti fails to consider. Plaintiffs' arguments that Mr. Kosty has not published in "academic peer-reviewed [economics] literature" and lacks teaching experience (Pls.' Br. at 5) may go to the weight a factfinder should give his testimony, but they do not render him unqualified. *See, e.g.*, *Dolfman v. Edwards*, Nos. 13-2831, 13-6172, 2015 WL 3477736, at *1 (E.D. Pa. June 2, 2015) ("lack of scholarly publications and peer-reviewed research for the past 20 years" could be "relevant to the weight the jury should give [expert's] testimony, not admissibility"). In short, the fact that Mr. Kosty is not an economist does not change the fact that he has decades of experience in the pharmacy industry, which more than qualify him to critique the damages opinions of Dr. Conti.

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[2] Plaintiffs rely on *Florio v. Ryobi Technologies, Inc.*, but that case is inapposite because it involved a purported expert witness with no experience whatsoever, including practical experience, with the product at issue. *See* No. 17-5518, 2020 WL 5234924, at *5 (D.N.J. Sept. 2, 2020) ("Insofar as he familiarized himself with relevant standards, it was only in preparing to testify in this lawsuit."), *appeal dismissed*, No. 20-2857, 2021 WL 982250 (3d Cir. Feb. 2, 2021).

B. Mr. Kosty's Opinions Are Based On A Reliable Methodology And Are Helpful.

Plaintiffs also attack Mr. Kosty's critiques of Dr. Conti's opinions as unreliable, but their assertions misrepresent the testimony Mr. Kosty gave at his deposition, distort the Court's prior ruling denying Defendants' motion to dismiss and misperceive the relevant burden of proof.

First, there is no truth to Plaintiffs' argument that Mr. Kosty retreated from his opinions at his deposition and accepted Dr. Conti's theory that the VCDs at issue in this litigation were categorically worthless. (*See* Pls.' Br. at 6.) Rather, he merely acknowledged that ***if*** it were "correct that" the VCDs were "without value" and "worthless," then "the proper measure of damages" would be "the full purchase price of the drug." (Kosty Dep. 143:4-144:11 ("In those hypotheticals and with those requirements, the answer is yes.").) That is little more than a tautology. If a product is worthless, of course anything paid for it would constitute damages. But the premise of the question assumes away the core disagreement between Mr. Kosty and Dr. Conti—i.e., whether the medications were in fact "worthless" in the first place.

Mr. Kosty's other supposed "admissions" were in much the same vein. After being read a snippet of the Food, Drug and Cosmetic Act, he confirmed that it prohibits adulterated drugs, but he never testified that such drugs were therefore economically worthless (or that the VCDs at issue in this litigation were in fact adulterated). (Kosty Dep. 121:10-123:21.) Mr. Kosty also acknowledged that in a

hypothetical world in which VCDs were not sold, there would be no supply curve. (*See id.* 156:14-17, 157:17-158:4.) Again, this is largely a tautology; if there were no supply there would not be a supply curve. But VCDs ***were*** actually sold, as Mr. Kosty went on to explain, creating an actual supply curve. (*See id.* 368:7-15.) And despite prodding from Plaintiffs' counsel, Mr. Kosty never accepted Dr. Conti's theory that there can be no economic price merely because an actual existing supply was retroactively deemed "illegitimate." Accordingly, the notion that Mr. Kosty "agree[d]" with Dr. Conti's opinions and somehow abandoned his own is foreclosed by the record.

In any event, even if Plaintiffs' view of the deposition were correct, the claim that an expert "allegedly contradicted himself in his expert report and deposition affects the weight and credibility of [his] testimony, and not his qualifications or methods used to support his opinion." *Buddy's Plant Plus Corp. v. CentiMark Corp.*, 978 F. Supp. 2d 523, 533 (W.D. Pa. 2013) (denying motion to exclude based on argument that expert's report and deposition were inconsistent), *aff'd*, 604 F. App'x 134 (3d Cir. 2015); *see, e.g.*, *Tuft v. Indem. Ins. Co. of N. Am.*, No. 19-cv-01827-REB-KLM, 2021 WL 1037863, at *3 (D. Colo. Jan. 29, 2021) (explaining that "deposition testimony [wa]s not contradictory" but if it had been, that would be "a matter [that went] to the weight, not the admissibility, of [the] opinion and can be

explored on cross-examination"). For this reason, too, Plaintiffs' arguments should be rejected.

Second, Plaintiffs also appear to argue (although their brief is not clear on this point) that Mr. Kosty's opinions criticizing Dr. Conti's theory of injury are contrary to "this Court's prior ruling[]" in its third motion to dismiss order. (Pls.' Br. at 6; *see* ECF 775.) However, as Defendants have explained in their class certification briefing, which is incorporated herein by reference, the Court's order denying the motion to dismiss merely accepted Plaintiffs' theory of injury on the pleadings. It did not purport to endorse Plaintiffs' theory as a matter of law, much less preclude anyone from challenging the theories put forth by Plaintiffs and their experts at class certification or any other evidentiary stage of the proceedings. (*See* Defs.' Mem. in Opp'n to Pls.' Mot. for Class Cert. of Cons. Econ. Loss Claims at 61-62 (ECF 2008); Mfr. & Pharm. Defs.' Mem. in Supp. of Mot. to Exclude Ops. of Dr. Rena Conti at 14-16 (ECF 2040-1); Defs.' (Proposed) Surreply in Further Opp'n to Pls.' Mot. for Class Cert. of Third-Party Payor Claims at 1-2 (ECF 2069-1).) This Court's prior ruling supplies no basis to call into question the reliability of Mr. Kosty's criticisms.

Third, Plaintiffs argue that Mr. Kosty's criticisms of Dr. Conti's opinions are unreliable because he failed to quantify certain factors relevant to a damages calculation. (Pls.' Br. at 7.) For instance, Plaintiffs argue that Mr. Kosty should be prohibited from critiquing Dr. Conti's failure to "account [for] certain offsets or

costs" because he "did not attempt to quantify" those costs himself. (*Id.*) Plaintiffs cite no authority suggesting—much less holding—that a defense expert criticizing the damages opinions of a plaintiff's expert must proffer his own calculations or models. Nor could they, as "the defense d[oes] not bear" the burden of proof either on the substantive merits of the lawsuit or the amenability of a case to class treatment. *Holbrook*, 80 F.3d at 786. Thus, "defendants' experts have . . . no burden to produce models or methods of their own." *Winn-Dixie Stores*, 2021 WL 2352016, at *14 (citation omitted); *see, e.g.*, *Capri Sun GmbH v. Am. Beverage Corp.*, No. 19 Civ. 1422 (PAE) (DCF), 2022 WL 976270, at *26 (S.D.N.Y. Mar. 31, 2022) ("At bottom, a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's."); *IceMOS Tech. Corp. v. Omron Corp.*, No. CV-17-02575-PHX-JAT, 2019 WL 4750129, at *10 n.9 (D. Ariz. Sept. 30, 2019) ("As a rebuttal witness, [expert] can rely on [opposing expert's] report to point out flaws in [his] analysis or conclusion" and "need not conduct an 'independent analysis'"); *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 29-30 (S.D.N.Y. 2020) (articulating this principle with respect to class certification opposition expert).

Finally, with respect to the Wholesalers specifically, Plaintiffs criticize Mr. Kosty because he "acknowledges" that the Court refused to order Wholesalers to produce cost data that could be relevant to Dr. Conti's unjust enrichment analysis. (Pls.' Br. at 7.) This argument is a red herring. Despite being aware of the existence

and relevance of chargebacks, discounts, rebates and the like, Dr. Conti never refers to them in her profit calculation in even the most general terms. (Dep. of Rena Conti, Ph.D. 138:14-24, 139:7-140:2, 142:20-143:7, 148:6-18, 149:10-150:15, Feb. 11, 2022 (Ex. 1).) Dr. Conti ignored those factors despite admitting that they may be relevant to calculating Wholesaler damages. Plaintiffs cannot now blame Wholesalers (and seek exclusion of an expert's opinions) because their proffered expert ignored relevant, well-known factors in her analysis. Wholesalers have not withheld any discovery from Plaintiffs; nor would any additional production (whether as to cost or pricing information) have assisted Dr. Conti in the critical part of her assignment to identify categories of costs that can later be populated to accurately determine Wholesaler profits. (*See* Wholesaler Defs.' Mem. in Supp. of Mot. to Exclude Ops. of Rena Conti at 3 n.2 (ECF 2037-1).)

For all of these reasons, Plaintiffs' criticisms of Mr. Kosty's damages-related opinions do not merit their exclusion.

II. MR. KOSTY'S ASCERTAINABILITY-RELATED OPINIONS ARE ADMISSIBLE.

Plaintiffs acknowledge that under Third Circuit law, the threshold requirement of ascertainability requires the party seeking class certification to demonstrate that there is "an 'administratively feasible mechanism for determining whether putative class members fall within the class definition.'" (Pls.' Br. at 12 (citation omitted).) That means showing, among other things, that class members

can be identified without depending on "the say-so of putative class members or . . . extensive and individualized fact-finding." *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 356 (3d Cir. 2013); *see id.* at 355 (quoting William B. Rubenstein, 1 *Newberg on Class Actions* § 3.3 (5th ed. 2011)) ("Administrative feasibility means that identifying class members in a manageable process that does not require much, if any, individual factual inquiry.").

Plaintiffs challenge several of Mr. Kosty's opinions related to this feasibility requirement, including his opinions that: (1) data to identify members of the various classes might not exist at all; (2) if they do, the data would be highly burdensome to collect; (3) combining the necessary disparate sources to ascertain members of the various classes would not be administratively feasible; (4) it is infeasible to track consumption in order to identify members of the putative medical monitoring class; (5) it would be equally infeasible to exclude Defendants' employees from the economic loss and medical monitoring classes; and (6) there is no feasible way to exclude government payors from the TPP class. None of Plaintiffs' arguments has any merit.

A. Mr. Kosty Reliably Opines That Necessary Data May Not Exist.

Plaintiffs argue that Mr. Kosty should be precluded from opining that certain "data" relevant to ascertaining the classes "might not exist," because he supposedly disclaimed this opinion at his deposition. (*See* Pls.' Br. at 9.) That is a gross

misrepresentation of Mr. Kosty's testimony. Mr. Kosty acknowledged that cash purchases of pharmaceuticals are recorded by the pharmacy (which would be relevant to ascertaining the consumer class) (*see* Kosty Dep. 132:2-6 (cited as "12:2:6" in Pls.' Br. at 9 n.28)), and that "data exists" regarding "what [an] insurance company pa[ys]" for certain medicines (which would be relevant to ascertaining the TPP class) (*see* Kosty Dep. 132:24-133:11 (cited in Pls.' Br. at 9 n.28)). But he did not address whether those data are preserved or would be available at the conclusion of this litigation. Nor did he address the important reality that given the complex "contractual arrangements between PBMs, TPPs, and intermediaries," any data that are available may not make clear exactly which entity or entities bore the ultimate financial burden, so as to come within the definition of the TPP class. (Kosty Rep. ¶ 90.)[3]

The other supposed admissions Plaintiffs highlight are even less helpful to their position. Mr. Kosty never suggested that "entities typically maintain pharmacy claims data for at least ten years." (Pls.' Br. at 9.) Indeed, he testified that it was

[3] Plaintiffs also recycle these same arguments in challenging Mr. Kosty's opinions related to the infeasibility of "distinguish[ing] between entities that . . . bore the ultimate financial risk" and "intermediaries that did not" to define the TPP class. (Pls.' Br. at 17 (asserting that "Mr. Kosty admits the data exist to make this distinction objectively and feasibly").) As discussed above, however, none of Mr. Kosty's testimony undermines his opinion regarding the potential unavailability of relevant data, including those indicating which entity bore the ultimate financial risk for reimbursements.

(cont'd)

"an individual business decision" "up to the individual pharmacy." (Kosty Dep. 226:16-20.) Although Medicare Part D programs are subject to a ten-year record-retention requirement, Mr. Kosty explained that PBMs and pharmacies are not subject to similar rules. (*See* Kosty Rep. ¶ 159; *see also* Kosty Dep. 226:12-13 ("Obviously, Med[icare Part] D is the longest period of time.").[4]

Nor did Mr. Kosty "admit[]" that "the top few PBMs and pharmacies" could by themselves provide data on "98 percent of class purchases." (Pls.' Br. at 9-10 (citation omitted).) In fact, he offered no opinion about that claim and explained that even if that were true, it would be time-consuming and expensive to gather and combine the data. (*See* Kosty Rep. ¶ 152; Kosty Dep. 254:20-255:2 ("I note that the time and expense required to obtain data from all these entities is the issue at hand here.").)

In short, the examples highlighted by Plaintiffs do not constitute "admissions" that undermine Mr. Kosty's fundamental opinion regarding the availability of data to ascertain class membership. But even assuming there were any truth to Plaintiffs' mischaracterizations, any inconsistencies between Mr. Kosty's report and his

[4] Plaintiffs presented documents at the deposition to suggest that one PBM and one retail pharmacy preserved documents related to Medicare Part D for ten years. However, Mr. Kosty explained that those isolated practices say nothing about more broadly-applicable preservation rules. (*See* Kosty Dep. 235:11-12 ("[I]t looks like this is applicable to Med[icare Part] D documents."), 236:6-8 ("For Med[icare Part] D, I would agree. I'm not sure about the other records. It does[not] specify.").)

deposition would "affect[] the weight and credibility of [his] testimony, and not" its admissibility. *Buddy's Plant Plus Corp.*, 978 F. Supp. 2d at 533.

B. Mr. Kosty Reliably Opines On The Difficulty And Burden Of Obtaining Data.

Plaintiffs also seek to exclude Mr. Kosty's opinion that, to the extent the data necessary to ascertain class membership are available, it would be burdensome and expensive to collect, combine and analyze that data. (*See* Pls.' Br. at 10-11.) This challenge, too, rests on mischaracterizations of Mr. Kosty's testimony and opinions.

First, Plaintiffs argue that Mr. Kosty "admit[ted]" that TPPs could obtain information related to payments from "their own PBMs, or a contracted intermediary." (Pls.' Br. at 10-11.) But Plaintiffs miss the point of Mr. Kosty's opinion, which is that ***even if*** TPPs could obtain information related to payments for VCDs from their own records, or from intermediaries like PBMs, the process would require a claims administrator "to individually contact potentially hundreds, if not thousands, of TPAs and TPPs to request that they identify their funding status . . . , review, and then reconcile all of their claims." (Kosty Rep. ¶ 106.) That is precisely the type of individualized inquiry that the Third Circuit has held makes a class unascertainable. *See, e.g.*, *Hayes*, 725 F.3d at 355, 361 (class was not ascertainable where there was "no method for determining how many of the 3,500 price-override transactions that took place during the class period were for as-is items" and within the scope of the class definition).

Second, Plaintiffs contend that Mr. Kosty conceded at his deposition that he would not "offer[] any opinions on archived data." (Pls.' Br. at 11.) But the possibility of data archiving is mentioned in just a single sentence of Mr. Kosty's hundred-page report, illustrating that it is not a meaningful component of his opinion regarding the costly and difficult nature of ascertaining class membership. Mr. Kosty's opinion on that score is well-supported by a host of other considerations, including the lack of a source to reliably distinguish between an end-payor and an intermediary, the fact that identifying TPP class members would require individualized inquiries, and Ms. Craft's failure to offer any method by which to reconcile disparate sources of data needed to determine the members of all three classes. (*See* Kosty Rep. ¶¶ 88-108.) Accordingly, Plaintiffs have not articulated any legitimate reason for excluding Mr. Kosty's well-reasoned opinions regarding the difficulties and burdens of collecting and analyzing the data necessary for ascertaining class membership.

C. Mr. Kosty Reliably Opines On The Challenges Of Combining Disparate Sources Of Data.

Plaintiffs also challenge Mr. Kosty's opinion regarding the difficulties associated with "linking . . . disparate data sources" and Ms. Craft's failure to account for those challenges in identifying the members of the consumer economic loss, TPP economic loss and medical monitoring classes. (Kosty Rep. ¶ 107.)

According to Plaintiffs, "[t]he Third Circuit does not require class plaintiffs to combine records showing class membership into a single mega-database" prior to class certification. (Pls.' Br. at 12.) But neither Defendants nor Mr. Kosty ever suggested that is required. Rather, as Plaintiffs themselves acknowledge, they ***do*** have to show "an 'administratively feasible mechanism for determining whether putative class members fall within the class definition'" that does not depend solely on the class members' own say-so. (*Id.* (quoting *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015)).) In other words, while Plaintiffs need not identify class members at this stage, they must show that they can reasonably do so (for all of their proposed classes) without individualized fact-finding. *See, e.g.*, *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013). And Mr. Kosty's opinions on the difficulties of combining disparate sources of data speak directly to whether that standard can or cannot be met (Kosty Rep. ¶ 107), a topic on which he has extensive experience, having worked on more than a dozen professional projects that involved integrating and combining claims data from two or more disparate sources across different business entities (Kosty Dep. 366:19-367:15), in contrast to Ms. Craft.

Plaintiffs also object that Mr. Kosty did not formally "quantify how much effort or 'manual review' it might take to combine data sources." (Pls.' Br. at 13 (quoting Kosty Dep. 220:6-12).) As mentioned above, however, a defense expert can identify factors that Plaintiffs' experts overlook without offering affirmative

opinions of his own. *See, e.g.*, *Capri Sun*, 2022 WL 976270, at *26 (a "rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's"). Plaintiffs also highlight that Mr. Kosty testified that the need for manual review does not categorically preclude identification of class members. (*See* Pls.' Br. at 13 (citing Kosty Dep. 219:16-22 (need for such review does not "mean that it[i]s administratively infeasible . . . to identify class members")).) But Mr. Kosty does not say otherwise in his report; rather, he explains that the need for potentially extensive individualized manual review is one of many factors that would make it extremely difficult to identify class members. (*See* Kosty Rep. ¶¶ 152-161.)

Although Plaintiffs highlight two supposed examples in which data from different sources were successfully merged, neither involved anything like the complex data sets at issue here. One example is taken from Mr. Kosty's "consulting practice." (Pls.' Br. at 13 (citing Kosty Dep. 250:18-254:10).) That example, which was undertaken to facilitate a corporate merger, involved just two different PBMs, rather than the dozens or hundreds of entities across multiple industries at issue here. (*See* Kosty Dep. 250:18-22; *id.* 367:4-9 (explaining that "95 percent of the time" his efforts to combine data only involve "two entities").) The other, from an "illustrative article," also involved just two entities (a pharmacy and a PBM) and just three months of data, rather than the several years at issue here. *See* William H. Shrank

et al., "The Epidemiology of Prescriptions Abandoned at the Pharmacy," 153 *Annals of Internal Medicine* 633 (2010).

Finally, Plaintiffs also contend that the only risk associated with the failure to successfully combine data sources is the potential for "duplicate entries," and that Mr. Kosty "readily admit[ted]" as much. (*See* Pls.' Br. at 14.) Not so. While Mr. Kosty agreed at his deposition that failure to adequately combine data raises the possibility of duplicate entries, he never suggested that was the ***only*** risk. (*See* Kosty Dep. 250:8-16 (cited in Pls.' Br. at 14 & n.50).) Inability to link disparate data sources also raises the substantial possibility of identifying the wrong class members, particularly for consumer class members, since many of them presumably share certain common names, and others might have changed their names during the class period. Accordingly, the Court should permit Mr. Kosty to opine about the difficulties associated with combining disparate data sources.

D. Mr. Kosty Reliably Opines On The Difficulties Of Creating Consumption Records To Define The Medical Monitoring Class.

Plaintiffs also seek to exclude all of Mr. Kosty's "opinions on creating 'consumption records'" (Pls.' Br. at 15) that are necessary for identifying the members of the proposed medical monitoring class, arguing that Mr. Kosty did not "test" whether records of different pharmacies used by the same consumer can be combined. (*Id.*) Mr. Kosty testified that there is "no universal patient identifier that allows one to track" individuals' prescription records across different pharmacies

during the class period, making it impossible to reliably determine lifetime cumulative thresholds of consumers to determine if they meet the criteria for inclusion in the proposed medical monitoring class. (Kosty Dep. 306:11-307:14.) This opinion did not require him to perform any "tests," and it is Plaintiffs' obligation to prove ascertainability, not Defendants' obligation to disprove it. In any event, Plaintiffs' own expert, Ms. Craft, conceded the point, testifying that she "was not able to match records for consumers across pharmacies."[5] (Dep. of Laura Craft ("Craft Dep.") 342:22-344:7, Feb. 18, 2022 (Pls.' Br. Ex. 4).)

E. Mr. Kosty Reliably Opines On The Challenges Of Excluding Defendants' Employees.

Mr. Kosty also explains that "identifying [d]efendants' employees that need to be excluded" from the consumer and medical monitoring classes would "require extensive manual review." (Kosty Rep. ¶ 138; *see id.* ¶¶ 137-139.) Plaintiffs do not appear to challenge this opinion with respect to the medical monitoring class, effectively conceding its admissibility. And although Plaintiffs lodge various criticisms of Ms. Kosty's opinion with respect to the proposed consumer economic loss class, they lack merit.

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[5] Plaintiffs contend that Ms. Craft "explained in detail how this task could be accomplished programmatically," but the testimony they highlight deals with constructing consumption records across multiple manufacturers, within a single pharmacy. (Pls.' Br. at 16 n.56 (citing Craft Dep. 332:18-342:7).)

First, Plaintiffs contend that Mr. Kosty "only looked at [the] retail pharmacy defendants" in opining about the consumer economic loss class. (Pls.' Br. at 14 (capitalization altered).) This is factually untrue and beside the point. Mr. Kosty specifically addressed the number of U.S. employees for "a select number of" both Pharmacy ***and*** Wholesaler Defendants. (Kosty Rep. ¶ 138 & Table 3 (listing the number of employees for AmerisourceBergen, Cardinal Health and McKesson).) Although Mr. Kosty did not do the same for any Manufacturer Defendant, the defendant list was only intended to provide an example of "the high number of individuals that would need to be identified." (*Id.* ¶ 138.) In short, the fact that there are additional Defendants, and additional employees to exclude, makes the issue more complex, not simpler.

Second, Plaintiffs note that Mr. Kosty lists the number of employees nationwide, rather than in "the subset of states at issue here" with respect to the economic loss class. (Pls.' Br. at 14.) But that proposed class is not limited to a "subset of states"; through its various subclasses, it covers a whopping 52 states, territories and districts. (*See* Pls.' Class Definitions & Exclusions Table (ECF 1747-1).) And to the extent some claims, asserted against certain Defendants, are not advanced under the laws of every single state, Plaintiffs cannot seriously argue that it changes Mr. Kosty's fundamental point—i.e., that records for millions of individuals would have to be reviewed to determine proper exclusions.

Third, Plaintiffs argue that "Mr. Kosty has no basis to speculate that any [d]efendant" lacks employee records (Pls.' Br. at 14 (citing Kosty Dep. 314:18-316:10)), and that he declined to offer an opinion "on how much effort it would take any defendant to produce" such records (Kosty Dep. 317:9-15 (cited in Pls.' Br. at 15)). Putting aside that Plaintiffs' experts are the ones who bear the burden to answer such questions, Mr. Kosty's opinions do not depend on the lack of records or the burden associated with producing them. Rather, they are based on the need for painstaking individual work to cross-reference those records with prescribing data once they have been identified and produced. This would need to be performed regardless of "how many [of] Defendants' employees might" ultimately be found to "have actually purchased valsartan" (Pls.' Br. at 15)—a number that is almost certain to be in the thousands, given the frequency with which the drug was prescribed across the population.

F. Mr. Kosty Reliably Opines On The Challenges Of Excluding State-Government Entities.

In addition to challenging Mr. Kosty's opinions related to the exclusion of Defendants' employees, *see supra* § II.D, Plaintiffs seek exclusion of Mr. Kosty's "opinion on the feasibility" of excluding state-government payors from the TPP class. (Pls.' Br. at 16.) As Mr. Kosty explains, one important indicator of the difficulty in excluding state entities is the fact that Plaintiffs' own experts "apply inconsistent exclusions" and sometimes reach demonstrably wrong results. (Kosty

Rep. ¶ 128.) For instance, Mr. Kosty notes that "Dr. Conti *excludes* all Medicaid plans from her damages methodology, while Ms. Craft *includes* Medicaid managed care plans." (*Id.* ¶ 129 (footnote omitted).) Plaintiffs' brief ignores this example, presumably because there is no possible way to reconcile such inconsistent approaches to determining class membership.

Although Plaintiffs attempt to downplay certain of the other examples highlighted by Mr. Kosty, their efforts once again distort Mr. Kosty's deposition testimony. For example, Plaintiffs claim that "Mr. Kosty admit[ted] that . . . Dr. Conti, in fact *did* properly *exclude* [the New York State Nurses Association] from her damages analysis." (Pls.' Br. at 16 (citing Kosty Dep. 318:19-319:18).) But that "admi[ssion]" is consistent with Mr. Kosty's report, which explains that while ***Dr. Conti*** properly excluded the Association, "***Ms. Craft*** *include[d]* this entity in her TPP count." (Kosty Rep. ¶ 131 (some emphasis added).) And contrary to Plaintiffs' assertion, Mr. Kosty did not "admit[] that the Montana University System should *not* be excluded" from the class. (Pls.' Br. at 16-17 (citing Kosty Dep. 324:6-325:1).) Rather, he merely acknowledged that a document presented to him suggested that in 2021—after the proposed class period ended—the Montana University System ran a self-funded plan. (*See* Kosty Dep. 325:6-11.) If so, that only underscores Mr. Kosty's point because self-funded plans must be excluded from the class definition to the extent that the self-funder is a state entity (*see, e.g.*, Rep. of Laura R. Craft ¶¶

55, 62, Nov. 10, 2021 (Pls.' Br. Ex. 3))—a fundamental fact that Plaintiffs ignore in their brief. In any event, Mr. Kosty's examples demonstrate that there is no systematic way to determine the funding status of *any* entity identified in the IQVIA data relied on by Plaintiffs' experts.

III. MR. KOSTY'S OPINIONS REGARDING THE ORANGE BOOK ARE ADMISSIBLE.

Based on his experience "serving on various P&T committees," Mr. Kosty also opines that those committees "use the Orange Book to determine the equivalence rating for generic drugs" but do not "consider [it] to represent any sort of warranty," and that Dr. Panagos is wrong to suggest to the contrary. (Kosty Rep. ¶¶ 195-196, 201.) He further states that P&T committees "rely on a wide range of documents" including, but not limited to, the Orange Book to develop their formularies, and "TPPs do not [otherwise] rely on the Orange Book for decisions to reimburse members' claims." (*Id.* ¶¶ 195-199.)

Plaintiffs' challenges to this opinion are not entirely clear, but they appear to make at least a half-hearted challenge to Mr. Kosty's qualifications. If so, the argument is nonsensical. As discussed above, an expert can be qualified based on "experience," *In re Actiq*, 2014 WL 3572932, at *3, and Mr. Kosty has practical experience in spades, having served on P&T committees himself (*see* Kosty Rep. ¶¶ 5, 196). Thus, Plaintiffs' conclusory argument that he "lacks any professional experience" on "drug reimbursement decisions" is flatly wrong, and their argument

that he fails to "identify any prior experience . . . ***advising***" TPPs or P&T committees is incorrect. (Pls.' Br. at 18 (citation omitted).)

Plaintiffs' reliability challenge—that Mr. Kosty "d[id] not rely on any facts . . . save for one source that he now admits supports [Dr.] Panagos'[s] opinion" (*id.*)—is equally frivolous. Mr. Kosty was entitled to rely on his extensive experience, *see, e.g.*, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (discussing standards for admitting expert testimony based on personal experience), and in any event, his report cited a host of sources, not just one, to support his opinion (*see* Kosty Rep. ¶¶ 195-203 & nn.354-367). Although Mr. Kosty testified that one of those sources suggests that P&T committees "are encouraged to rely" upon certain representations in the Orange Book (Kosty Dep. 360:9-19 (cited in Pls.' Br. at 18)), that in no way undermines the soundness of Mr. Kosty's opinion. After all, Mr. Kosty never suggested that P&T committees ignore the Orange Book altogether; rather, he opines that P&T committees do not consider statements made in the Orange Book to constitute "any sort of warranty." (Kosty Rep. ¶¶ 195-196, 201).) Plaintiffs fail to explain how any of the sources cited by Mr. Kosty undermines that relevant opinion.

Finally, Plaintiffs are wrong that Mr. Kosty's opinion that an Orange Book listing is not considered a warranty should be excluded because they consider it nothing more than "dicker[ing] with a single word choice." (Pls.' Br. at 18.) Here,

however, the "word choice" concerns whether the Orange Book creates a "warranty": a central issue in this litigation. The first four causes of action advanced on behalf of the consumer and TPP classes sound in warranty, as do two claims advanced on behalf of the medical monitoring class, and the claims for breach of express warranty specifically allege that Defendants "expressly warranted [that VCDs] were compliant with . . . Orange Book requirements." (Third Am. Econ. Loss Compl. ¶ 623 (ECF 1708); Third Am. Med. Mon. Compl. ¶ 649 (ECF 1709) (same); *see* Third Am. Econ. Loss. Compl. p. 123 & ¶¶ 411-412 (describing inclusion in the Orange Book as a "warrant[y] common to all manufacturer defendants") (capitalization altered); Third Am. Med. Mon. Compl. p. 124 & ¶ 354 (similar).) Consistent with these allegations and causes of action, Plaintiffs' expert, Dr. Panagos, seeks to opine that placement in the Orange Book "represents a manufacturer's warranty to TPPs and P&T [c]ommittees." (Rep. of Kali Panagos ¶ 47, Nov. 10, 2021 (Ex. 2).) Having placed the issue squarely in dispute, Plaintiffs cannot now complain that Mr. Kosty offers an opinion about it. Regardless, Plaintiffs cite no authority for the proposition that an expert opinion is inadmissible merely because the opposing party does not believe the issue to be sufficiently important. Plaintiffs' disagreement with the importance of the word "warranty" is a matter for cross-examination, not a basis for excluding an expert's opinion. *See generally Daubert*, 509 U.S. at 596 ("[v]igorous cross-examination [and]

presentation of contrary evidence" are ordinary means for attacking opponent's evidence).

In short, Plaintiffs' attempt to exclude Mr. Kosty's opinion related to the Orange Book misapprehends the relevant opinion in question, Mr. Kosty's testimony and the nature of Plaintiffs' own claims and allegations in this litigation.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion to partially exclude the opinions of Mr. Timothy Kosty should be denied in its entirety.

Dated: June 2, 2022

Respectfully submitted,

By: */s/ Jessica Davidson Miller*
Jessica Davidson Miller (DC Bar No. 457021)
Liaison Counsel for Manufacturer Defendants
Nina R. Rose (DC Bar No. 975927)
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Telephone: (202) 371-7000
Facsimile: (202) 661-0525
jessica.miller@skadden.com
nina.rose@skadden.com

Attorneys for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC

Lori G. Cohen, Esq.
GREENBERG TRAURIG, LLP
Victoria Davis Lockard

Steven M. Harkins
Terminus 200
3333 Piedmont Rd., NE,
Suite 2500
Atlanta, Georgia 30305
Tel: (678) 553-2385
Fax: (678) 553-2386
cohenl@gtlaw.com
lockardv@gtlaw.com
harkinss@gtlaw.com

Gregory E. Ostfeld
Tiffany M. Andras
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601
Tel: (312) 456-8400
ostfeldg@gtlaw.com
andrast@gtlaw.com

Brian H. Rubenstein
1717 Arch Street, Suite 400
Philadelphia, Pennsylvania
Tel: (215) 988-7864
Fax: (214) 689-4419
rubensteinb@gtlaw.com

Attorneys for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc.

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
Clem C. Trischler
Jason M. Reefer
Frank H. Stoy
38th Floor, One Oxford Centre
Pittsburgh, Pennsylvania 15219
Tel: (412) 263-2000

Fax: (412) 263-2001
cct@pietragallo.com
jmr@pietragallo.com
fhs@pietragallo.com

Attorneys for Mylan Laboratories, Ltd. and Mylan Pharmaceuticals, Inc.

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
devora.allon@kirkland.com
alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

MORGAN, LEWIS & BOCKIUS LLP
John P. Lavelle, Jr.
1701 Market Street
Philadelphia, Pennsylvania 19103
Tel. (215) 963-5000
Fax (215) 963-5001
john.lavelle@morganlewis.com

John K. Gisleson
One Oxford Centre, Thirty-Second Floor
Pittsburgh, Pennsylvania 15219
Tel. (412) 560-3300
Fax (412) 560-70001
john.gisleson@morganlewis.com

Attorneys for Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC

LEWIS BRISBOIS BISGAARD & SMITH LLP
Walter H. Swayze, III
Andrew F. Albero
550 E. Swedesford Road, Suite 270
Wayne, Pennsylvania 19087
Tel: (215) 977-4100
Fax: (215) 977-4101
Pete.Swayze@lewisbrisbois.com
Andrew.Albero@lewisbrisbois.com

Attorneys for Camber Pharmaceuticals, Inc.

HILL WALLACK LLP
Eric I. Abraham
William P. Murtha
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08543-5226
Tel.: (609) 734-6358
Fax: (609) 452-1888
eabraham@hillwallack.com
wmurtha@hillwallack.com

Attorneys for Hetero Drugs, Ltd. and Hetero Labs Ltd.

HARDIN KUNDLA MCKEON & POLETTO
Janet L. Poletto, Esq.
Robert E. Blanton, Jr., Esq.
673 Morris Ave.
Springfield, New Jersey 07081
Tel. (973) 912-5222
Fax (973) 912-9212
jpoletto@hkmpp.com
rblanton@hkmpp.com

Attorneys for Hetero USA Inc.

Jeffrey D. Geoppinger, Esq.
Liaison Counsel for Wholesalers
ULMER & BERNE LLP
312 Walnut Street, Suite 1400
Cincinnati, OH 45202-2409
Tel.: (513) 698-5038
Fax: (513) 698-5039
Email: jgeoppinger@ulmer.com

Counsel for AmerisourceBergen Corporation

Andrew D. Kaplan
Daniel T. Campbell
Marie S. Dennis
Emily G. Tucker
Luke J. Bresnahan
CROWELL & MORING
1001 Pennsylvania Avenue NW
Washington, D.C. 20004
Tel.: (202) 624-1000
Fax: (202) 628-5116
Email: akaplan@crowell.com
Email: dcampbell@crowell.com
Email: mdennis@crowell.com
Email: etucker@crowell.com
Email: lbresnahan@crowell.com

Counsel for Cardinal Health, Inc.

D'Lesli M. Davis
Ellie K. Norris
NORTON ROSE FULBRIGHT US LLP
2200 Ross Avenue, Suite 3600
Dallas, TX 75201-7932
Tel: (214) 855-8221
Fax: (214) 855-8200

Email:
dlesli.davis@nortonrosefulbright.com
Email: ellie.norris@nortonrosefulbright.com

Counsel for McKesson Corporation

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 2, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson Miller*
Jessica Davidson Miller (DC Bar No. 457021)